

Exhibit H



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/003,996	11/15/2001	Peter M. Bonutti	BON-1360-8	8298

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MIAMI, FL 33131

EXAMINER

BAXTER, JESSICA R

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 06/23/2003 18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/003,996

Applicant(s)

BONUTTI, PETER M.

Examiner

Jessica R Baxter

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36-47,49 and 51-76 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36-47,49 and 51-76 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Terminal Disclaimer

1. The terminal disclaimer filed on March 31, 2003 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent No. 5,403,317 has been reviewed and is accepted. The terminal disclaimer has been recorded.
2. The terminal disclaimer filed on March 31, 2003 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent No. 5,694,951 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 61-61-68 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification fails to point out that the blood and other body tissue are free from tanning substances.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 36-39, 42-47 and 49 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 5,226,877 to Epstein.

Regarding claims 36, 37, 42 and 44, Epstein discloses a surgical procedure comprising the steps of removing tissue comprised of blood from a first location (Column 6 lines 1-4), separating one or more components from at least a portion of the tissue by centrifugation (Column 7 lines 13-23), and implanting the packed tissue at a second location (Column 10 lines 45-60).

Regarding claim 38, Epstein discloses that a further step of adding a substance to the body tissue (Column 6 lines 37-61) after separating one or more substances from the tissue and prior to implanting the body tissue at a second location in the patient's body.

Regarding claim 39, Epstein discloses that the step of cutting the body tissue at the first location and moving the body tissue away from the first location under the influence of suction (Column 7 lines 13-23).

Regarding claim 43 and 45, Epstein discloses that the step of removing tissue includes removing blood and other tissue, said step of separating one or more components includes

separating a component from the blood and then implanting the other tissue and blood at a second location (Column 1 lines 37-45 and Column 10 lines 53-60).

Regarding claim 46, Epstein discloses that said step of separating one or more components from the body tissue includes filtering the tissue (see Column 6 lines 1-61).

Regarding claim 47, Epstein discloses the step of moving the removed tissue into a trap before implanting (Column 7 lines 31-52).

Regarding claim 49, Epstein discloses the use of a first tubular member to remove tissue from a first location (Column 7 lines 13-23) and said step of implanting tissue includes inserting a second tubular member into the patient's body and moving tissue through the second tubular member (Column 10 lines 53-60).

5. Claims 36, 38 and 61-65 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 5,073,373 to O'Leary et al.

O'Leary discloses a surgical procedure comprising the steps of removing tissue and blood (Column 1 lines 18-24 and Column 2 line 52-Column 3 line 14) from a first location, separating one or more components from at least a portion of the tissue (Column 2 lines 14-43), packing the tissue and implanting the packed tissue at a second location (Column 4 lines 13-45), and adding a substance to the packed tissue (Column 2 line 44-Column 3 line 15).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary

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skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 39, 40, 49, 51, 53-55, 57-60, 66, 69, 71 and 73-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Leary '373 in view of U.S. Patent No. 4,573,448 to Kambin.

O'Leary discloses the claimed invention except for the first tubular member used to cut the tissue from the first location. Kambin teaches a bone-cutting instrument that provides a rotatable cutter and suction (Column 3 lines 47-56). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the method of O'Leary with the bone cutter of Kambin since Kambin's bone cutter is used to remove bone fragments, which can be used in the method of O'Leary to make the desired bone paste.

7. Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over O'Leary in view of U.S. Patent No. 4,936,848 to Bagby.

O'Leary discloses the claimed invention except for the removal of tissue from the second location. Bagby teaches that diseased tissue must be removed before an implant is inserted into the body (Column 4 lines 54-60). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the method of O'Leary with the step of removing tissue from the second location in order to remove diseased or damaged tissue before the implant was inserted.

8. Claims 52, 67, 68, 70 and 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Leary '373 in view of Kambin 448 as applied above, and further in view of U.S. Patent No. 4,828,563 to Muller-Lierheim and U.S. Patent No. 4,210,580 to Amrani.

O'Leary, as modified, discloses the closed invention except for centrifuging the blood or body tissue to separate one or more components from the blood. Muller-Leirheim teaches that growth factors, particularly fibronectin, are added to bone implants to enhance biocompatibility and

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mechanical strength (Column 1 line 37-Column 2 line 7). Amrani teaches that fibronectin may be obtained from blood plasma by centrifuging the blood plasma (Column 2 lines 26-30). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the method of O'Leary with the additional step of centrifuging blood to obtain fibronectin, an additive to an implant material, to enhance the biocompatibility and strength of the O'Leary implant material.

9. Claims 56 and 76 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Leary '373 in view of Kambin '448 as applied above, and further in view of Bagby '848.

O'Leary, as modified, discloses the claimed invention except for the removal of tissue from the second location. Bagby teaches that diseased tissue must be removed before an implant is inserted into the body (Column 4 lines 54-60). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the method of O'Leary, as modified, with the step of removing tissue from the second location in order to remove diseased or damaged tissue before the implant was inserted.

Response to Arguments

10. Applicant's arguments with respect to claims 36-47, 49 and 51-76 have been considered but are moot in view of the new ground(s) of rejection.


Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica R Baxter whose telephone number is 703-305-4069. The examiner can normally be reached on M-F 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Jessica R Baxter
Examiner
Art Unit 3731


June 16, 2003


MICHAEL J. MILANO
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700